

REMARKS

Summary of the Office Action

Claims 1-3, 8, 10, 16, and 21-24 are pending in the present application.

Claims 22-24 are objected to as being in improper dependent form.

Claims 1-3, 8, 16, and 23-24 have been rejected under 35 U.S.C. 103(a) as obvious over European Patent Application EP 0 779 062 to Glastra ("*Glastra*") in view of German Patent No. DE 195 09 464 to Jäger ("*Jäger*").

Claim 10 has been rejected under 35 U.S.C. 103(a) as obvious over *Glastra* in view of *Jäger* and further in view of U.S. Patent No. 5,695,498 to Tower ("*Tower*").

Claim 21 has been rejected under 35 U.S.C. 103(a) as obvious over *Glastra* in view of *Jäger* and further in view of U.S. Patent No. 6,120,534 to Ruiz ("*Ruiz*").

Claim 22 has been rejected under 35 U.S.C. 103(a) as obvious over *Glastra* in view of *Jäger* and further in view of U.S. Patent No. 5,843,116 to Crocker ("*Crocker*").

Response to the Office Action

A. Introduction

Claims 1-3, 8, 10, 16 and 21-24 are pending in the application. Claims 1, 10, 16, 23 and 24 have been amended, claim 22 has been canceled, and new claims 25-29 have been added. Therefore, upon entry of the present amendment, claims 1-3, 8, 10, 16 and 21, and 23-29 will be subject to examination.

Amendments to the claims and new claims have been introduced to point out the claimed invention with greater clarity, namely, a stent-catheter arrangement and related methods of use developed for throttling blood flow in a patient. One method of use developed by Assignee Abbott is the treatment of conditions such as excessive blood flow in the pulmonary vessel of babies with Patent Ductus Arteriosus. The stent-catheter arrangements and the related methods disclosed and claimed in the present application enable not only a reduction of blood flow, but also an expansion of the stent over time as the baby grows or the pathological condition is otherwise improved.

The Examiner has not asserted that any claims in the application are anticipated by the cited prior art, but instead has rejected the pending claims as obvious in view of the cited references. Applicant respectfully traverses the pending rejections.

B. The Rejections under 35 U.S.C. 103(a)

To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 180 USPQ 580 (CCPA 1974). If an independent claim is non-obvious under 35 U.S.C. 103, then any claim depending therefrom is non-obvious. *In re Fine*, 5 USPQ2d 1596 (Fed. Cir. 1988). See also MPEP 2143.03.

The rejection of claims 1-3, 8, 16, and 23-24 over *Glastra* in view of *Jäger* is respectfully traversed because the combination of *Glastra* and *Jäger* does teach all the elements of independent claim 1 as currently amended.

Glastra discloses a method for forming a stent, which is configured to maintain patency in a vessel constricted by a nearby tumor, which exerts pressure on a wall of the vessel. FIG. 6 (cited by the Examiner) and the written description of *Glastra* teach that the *Glastra* stent has a substantially cylindrical central section 31 and diverging end sections 32.

The Examiner has cited *Glastra* as a primary reference disclosing all the elements of the claimed invention except for a liquid impermeable cover over the stent or a stiffening element for forming a reduced expandable section. Applicant notes that this is not correct, because *Glastra* does not teach or suggest “said balloon being configured and arranged to expand said stent to form first and second essentially tubular fixing portions and an essentially tubular portion coupled to said first and second expanded fixing portions by first and second tapering portions of predetermined lengths and angles” and that “said essentially tubular portion is radially spaced from the interior wall of the vessel.” An analysis of *Glastra* reveals that the *Glastra* stent has no fixing portions, and also that the central portion of the *Glastra* stent is not configured to be radially spaced from a vessel wall.

Moreover, while *Glastra* discloses using a preformed balloon, such balloon is not shaped to produce Applicant’s deployed stent, as can be seen by comparing FIG. 6 of *Glastra* (showing a balloon having outer portions that push on the vessel wall to create an angle) with FIG. 11 of Applicant (showing a balloon having outer portions of tubular shape).

Furthermore, *Glastra* does not teach “one or more segments of said balloon being selectively stiffened,” because *Glastra* does not teach having the central segment of his stent separated from the vessel walls, but on the contrary requires the central segment to make contact with the vessel wall in the constricted region. In fact, the inventions of *Glastra* and of Applicant are directed to solving opposite problems, namely, to maintain a vessel open in *Glastra*, and to narrow blood flow in Applicant’s invention.

Glastra also does not teach “a tapered section configured to essentially prevent blood turbulence,” because blood turbulence is not discussed at all in the *Glastra* patent.

Jäger has been cited by the Examiner as providing the missing elements in *Glastra* of a liquid impermeable cover over the stent and a stiffening element for forming a reduced expandable section. Applicant notes that this is not correct, because *Jäger* teaches (as best understood) that “the chokepoint 5 [of the stent] can for example be stabilized by a wire wound around the chokepoint 5 or by a spring clip.” Therefore, *Jäger* does not teach that the stent is formed by stabilizing the central portion of the balloon, but instead by constricting the central portion of the stent. Applicant could find no reference to expansion balloons in *Jäger*, and Applicant’s claim 1 as currently amended makes no reference to stabilizing the central portion of the stent by adding stiffening elements to the stent.

As to the impermeable cover, Applicant acknowledges that such cover is mentioned in *Jäger*, although *Jäger* teaches that such cover is used to prevent intimal hyperplasia and not to throttle blood flow, providing Applicant with no reason to combine this feature with other features of Applicant’s invention, contrary to the requirements for a prima facie obviousness rejection.

Therefore, the combination of *Glastra* and *Jäger* does not teach all the elements of Applicant’s invention, rendering non-obvious claim 1 and the claims depending therefrom.

Applicant would like to briefly comment on the other references cited by the Examiner with regard to certain of the dependent claims.

Tower has been cited with regard to claim 10 as teaching at col. 3, lines 21-34 that “the balloon is formed of stiffened balloon material and that the reduced expandability section is formed during balloon production.” As best understood, *Tower* teaches a stent implantation system that includes a balloon that is preformed during manufacture such that it will acquire a predetermined shape when inflated to a first pressure and become cylindrical when pressure is

further increased. Contrary to the examiner's assertion, *Tower* explains that the balloon is manufactured using only "a thin wall membrane." *Tower*, col. 3, lines 17-18. Regardless of *Tower*, claim 1, from which claim 10 depends, is non-obvious for the reasons discussed above, making claim 10 non-obvious *per se*.

Ruiz has been cited with regard to claim 21 as teaching that the stent may be covered with PTFE. Applicant notes that that claim 1, from which claim 21 depends, is non-obvious for the reasons discussed above, making claim 21 non-obvious *per se*.

Crocker has been cited with regard to claim 22 as teaching that a stiffening element may be integrated into the balloon. Applicant notes that *Crocker* teaches the use of stiffening elements to control expansion of certain portions of the balloon, leaving the remainder free to expand otherwise, but does not teach, for example, using or disposing stiffening elements to create shapes that control blood turbulence. More particularly, *Crocker* teaches that the end portions of a balloon may be lobe-shaped, without the profile as claimed by Applicant. Regardless of *Crocker*, claim 1, from which claim 22 depends, is non-obvious for the reasons discussed above, making claim 10 non-obvious *per se*.

Based on the foregoing, the withdrawal of all rejections under 35 U.S.C. 103(a) is respectfully requested.

C. The Improper Dependencies

Claim 22 has been canceled, claim 23 has been amended to depend from claim 1, and claim 24 as been amended to depend from claim 23. Therefore, it is believed that all dependencies in the application are now in proper form.

D. The New Claims

Claims 25-29 are directed to subject matter fully supported in the specification. No new matter has been added.

Conclusion

Applicant believes that all points raised by the Examiner have been addressed and that the application is now in condition for allowance. The timely issue of a notice to that effect is respectfully requested. If necessary, the Commissioner is hereby authorized in this and concurrent replies to charge payment (or credit any overpayment) to Deposit Account No. 50-2298 for any additional required fees.

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Respectfully submitted,

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